

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 03-839-C)

In re Application of:	)	
	)	
Pan et al.	)	Examiner:
	)	
Serial No.	)	
	)	Group Art Unit:
Filed: April 8, 2004	)	
	)	
For: Modified IL-4 Mutein	)	Confirmation No.:
Receptor Antagonists	)	

Mail Stop PATENT APPLICATION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In order to comply with discretionary regulations 37 CFR §§1.97 and 1.98, attached hereto is Form PTO SB/08, copies<sup>1</sup> of the documents listed thereon. These documents contain information which the Examiner may consider to be important in deciding whether to allow the present application to issue as a patent.

1. Ying S., et al., "Expression of IL-4 and IL-5 mRNA and Protein Product by CD4<sup>+</sup> and CD8<sup>+</sup> T Cells, Eosinophils, and Mast Cells in Bronchial Biopsies Obtained from Atopic and Nonatopic (Intrinsic) Asthmatics," *J. Immunol.*, 158(7):3539-3544 (1997 Apr 1)
2. Huang S., et al., "IL-13 Expression at the Sites of Allergen Challenge in Patients with Asthma," *J. Immunol.*, 155(5):2688-2694 (1995 Sep 1)

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<sup>1</sup>To the extent that a document is listed and no copy of same is attached, then such document is not at the present time available to the undersigned or is available in the file of a parent application. If a listed document is not in the English language and an English translation is readily available, such translation is also attached; if translation is not attached it is not readily available to the undersigned. If a foreign language patent document is cited, and an English language equivalent is known to the undersigned, then such equivalent patent is also cited on the attached form along with the corresponding foreign language patent and a connecting arrow indicated there between; if no such English language equivalent is cited, then none is known to undersigned.

3. Zhu Z., et al., "Pulmonary expression of interleukin-13 causes inflammation, mucus hypersecretion, subepithelial fibrosis, physiologic abnormalities, and eotaxin production," *J. Clin. Invest.*, 103(6):779-788 (March 1999)
4. Henderson W., et al., "Soluble IL-4 Receptor Inhibits Airway Inflammation Following Allergen Challenge in a Mouse Model of Asthma," *J. Immunol.*, 164(2):1086-1095 (2000 Jan 15)
5. Levens JM, et al., "Micro-environmental factors in the survival of human B-lymphoma cells," *Cell Death Differ.*, 7:59-69 (2000)
6. Myers J., et al., "Growth Stimulation of Human Head and Neck Squamous Cell Carcinoma Cell Lines by Interleukin 4," *Clin Cancer Res.*, 2:127-135 (January 1996)
7. Newcom SR, et al., "Interleukin-4 Is an Autocrine Growth Factor Secreted by the L-428 Reed-Sternberg Cell," *Blood*, 79(1):191-197 (January 1 1992)
8. Gée K., et al., "Differential Effect of IL-4 and IL-13 on CD44 Expression in the Burkitt's Lymphoma B Cell Line BL30/B95-8 and in Epstein-Barr Virus (EBV) Transformed Human B Cells: Loss of IL-13 Receptors on Burkitt's Lymphoma B Cells," *Cell Immunol.*, 211:131-142 (2001)
9. Kryworuchko M., et al., "Regulation of CD44-Hyaluronan Interactions in Burkitt's Lymphoma and Epstein-Barr Virus-Transformed Lymphoblastoid B Cells by PMA and Interleukin-4," *Cell Immunol.*, 194:54-66 (1999)
10. Kruse N., et al., "Conversion of human interleukin-4 into a high affinity antagonist by a single amino acid replacement," *Embo J.*, 11(9):3237-3244 (1992)
11. Tony H., et al., "Design of human interleukin-4 antagonists inhibiting interleukin-4-dependent and interleukin-13-dependent responses in T-cells and B-cells with high efficiency," *Eur. J. Biochem.*, 225:659-665 (1994)

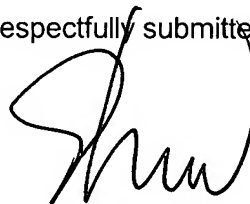
In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO SB/08) be given thorough consideration and that it be cited of record in the

prosecution history of the present application by initialing on Form PTO SB/08. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Disclosure Statement is being submitted in compliance with 37 CFR 1.56 insofar as an Examiner might consider any of the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of each document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,



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Emily Miao  
Registration No. 35,285

Dated: April 8, 2004

McDonnell Boehnen Hulbert & Berghoff LLP  
300 South Wacker Drive  
Chicago, Illinois 60606  
Telephone : (312) 913-0001  
Facsimile: (312) 913-0002

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PTO/SB/08B (08-00)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application No.	
				Filing Date: <b>April 8, 2004</b>	
				First Named Inventor <b>Pan</b>	
				Group Art Unit	
Examiner Name				unassigned	
Attorney Docket No.				03-839-C	
Sheet	1	of	1		

# OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	1	<b>YING S., ET AL.</b> , "Expression of IL-4 and IL-5 mRNA and Protein Product by CD4 <sup>+</sup> and CD8 <sup>+</sup> T Cells, Eosinophils, and Mast Cells in Bronchial Biopsies Obtained from Atopic and Nonatopic (Intrinsic) Asthmatics," <i>J. Immunol.</i> , 158(7):3539-3544 (1997 Apr 1)	
	2	<b>HUANG S., ET AL.</b> , "IL-13 Expression at the Sites of Allergen Challenge in Patients with Asthma," <i>J. Immunol.</i> , 155(5):2688-2694 (1995 Sep 1)	
	3	<b>ZHU Z., ET AL.</b> , "Pulmonary expression of interleukin-13 causes inflammation, mucus hypersecretion, subepithelial fibrosis, physiologic abnormalities, and eotaxin production," <i>J. Clin. Invest.</i> , 103(6):779-788 (March 1999)	
	4	<b>HENDERSON W., ET AL.</b> , "Soluble IL-4 Receptor Inhibits Airway Inflammation Following Allergen Challenge in a Mouse Model of Asthma," <i>J. Immunol.</i> , 164(2):1086-1095 (2000 Jan 15)	
	5	<b>LEVEN S JM, ET AL.</b> , "Micro-environmental factors in the survival of human B-lymphoma cells," <i>Cell Death Differ.</i> , 7:59-69 (2000)	
	6	<b>MYERS J., ET AL.</b> , "Growth Stimulation of Human Head and Neck Squamous Cell Carcinoma Cell Lines by Interleukin 4," <i>Clin Cancer Res.</i> , 2:127-135 (January 1996)	
	7	<b>NEWCOM SR, ET AL.</b> , "Interleukin-4 Is an Autocrine Growth Factor Secreted by the L-428 Reed-Sternberg Cell," <i>Blood</i> , 79(1):191-197 (January 1 1992)	
	8	<b>GEE K., ET AL.</b> , "Differential Effect of IL-4 and IL-13 on CD44 Expression in the Burkitt's Lymphoma B Cell Line BL30/B95-8 and in Epstein-Barr Virus (EBV) Transformed Human B Cells: Loss of IL-13 Receptors on Burkitt's Lymphoma B Cells," <i>Cell Immunol.</i> , 211:131-142 (2001)	
	9	<b>KRYWORUCHKO M., ET AL.</b> , "Regulation of CD44-Hyaluronan Interactions in Burkitt's Lymphoma and Epstein-Barr Virus-Transformed Lymphoblastoid B Cells by PMA and Interleukin-4," <i>Cell Immunol.</i> , 194:54-66 (1999)	
	10	<b>KRUSE N., ET AL.</b> , "Conversion of human interleukin-4 into a high affinity antagonist by a single amino acid replacement," <i>Embo J.</i> , 11(9):3237-3244 (1992)	
	11	<b>TONY H., ET AL.</b> , "Design of human interleukin-4 antagonists inhibiting interleukin-4-dependent and interleukin-13-dependent responses in T-cells and B-cells with high efficiency," <i>Eur. J. Biochem.</i> , 225:659-665 (1994)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC. 20231